

Lardo et al.  
U.S.S.N. 09/904,182  
Page 6 of 10

RECEIVED  
CENTRAL FAX CENTER

JUL 12 2007

REMARKS

Claims 61-82 are pending. Claim 61 is amended, claim 68 is canceled, and claim 84 is added. No new matter is added by these amendments, support therefore being found throughout the application as filed (e.g. see page 6, lines 14-23).

1. 35 U.S.C. §103 REJECTIONS

**Motamedi, Swanson, and Altman**

Claims 61-63, 78-81, and 83 are rejected under 35 U.S.C. §103(a) over U.S. Patent No. 6,143,019 to Motamedi et al. (hereinafter "Motamedi"), U.S. Patent No. 6,023,638 to Swanson (hereinafter "Swanson"), and U.S. Patent No. 6,577,895 to Altman (hereinafter "Altman").

Applicants' amended independent claim 61 provides a non-thermal method for treating and/or curing cardiac arrhythmias. The method comprises administering a photosensitizing agent to at least one pulmonary vein, inserting an illumination device into the at least one pulmonary vein ostia before, during, or after administration of the photosensitizing agent, the illumination device comprising a fiberoptic housed within a balloon, and during and/or after the photosensitizing agent is administered, delivering illumination from the fiberoptic through the balloon so as to activate the photosensitizing agent in the pulmonary vein, thereby ablating a section of the pulmonary vein and electrically isolating the pulmonary vein from the left atrium.

New claim 84 is similar and recites a non-thermal method to treat and/or cure cardiac arrhythmias using photochemotherapy or photodynamic therapy to destroy tissues and pathways from which abnormal signals arise and/or in other cardiac tissues such that abnormal electrical rhythms can not be generated and/or sustained. The method comprises delivering a photosensitizing agent to the cardiac tissue, inserting an illumination device to the desired treatment site before, during, or after administration of the photosensitizing agent, the illumination device comprising a fiberoptic housed within a balloon, and during and/or after the photosensitizing agent is administered, delivering illumination from the fiberoptic through the balloon so as to activate the photosensitizing agent.

Motamedi, on the other hand, describes a catheter containing a movable conductor that is percutaneously advanced beyond the catheter body and into the myocardium. The tip of the conductor is configured to penetrate cardiac tissue for lateral diffusion of ablating energy into the intramyocardial tissue.

Motamedi does not teach or suggest inserting an illumination device into the pulmonary vein ostia, the illumination device comprising a fiberoptic housed within a balloon, and delivering illumination from the fiberoptic through the balloon. Motamedi also does not teach or suggest a method wherein an illumination device comprising a fiberoptic housed within a balloon is inserted to the desired treatment site and illumination is delivered from the fiberoptic through the balloon. Rather, Motamedi's device is specifically designed such that the tip of the conductor advances beyond the catheter body and penetrates and enters the cardiac tissue.

Swanson does not remedy these deficiencies. Swanson describes a catheter having a three-dimensional distal portion formed of splines 30 (e.g. in the form of a basket) that carry multiple electrodes 24. Swanson does not teach or suggest a method wherein an illumination device comprising a fiberoptic housed within a balloon is inserted to the desired treatment site and illumination is delivered from the fiberoptic through the balloon. Further, even if Swanson did describe such a method, there is no motivation to modify Motamedi so as to provide a balloon housing the conductor tip and delivering illumination from the conductor through the balloon because such a modification of Motamedi would render the device of Motamedi "unsuitable for its intended purpose" and would result in "a change in the basic principle under which [Motamedi] was designed to operate" (see MPEP 2143.01). In particular, providing Motamedi's conductor housed within a balloon would prevent it from advancing beyond the catheter body and penetrating and entering the cardiac tissue.

Altman also does not remedy these deficiencies. Altman describes a balloon catheter for delivering fluid into the pulmonary vein. Altman does not teach or suggest a method wherein an illumination device comprising a fiberoptic housed within a balloon is inserted to the desired treatment site and illumination is delivered from the fiberoptic through the balloon. Further,

Lardo et al.  
U.S.S.N. 09/904,182  
Page 8 of 10

even if Altman did describe such a method, there is no motivation to modify Motamedi so as to provide a balloon housing the conductor tip and delivering illumination from the conductor through the balloon because such a modification of Motamedi would render the device of Motamedi "unsuitable for its intended purpose" and would result in "a change in the basic principle under which [Motamedi] was designed to operate" (see MPEP 2143.01). In particular, providing Motamedi's conductor housed within a balloon would prevent it from advancing beyond the catheter body and penetrating and entering the cardiac tissue.

Thus, claims 61 and 84 are patentable over Motamedi, Swanson, and Altman. Claims 62, 63, 78-81, and 83 depend from claim 61 and, thus, also are patentable over Motamedi, Swanson, and Altman. Reconsideration and withdrawal of the rejection is respectfully requested.

#### **Motamedi, Swanson, Altman, and Leone**

Claims 64-77 are rejected under 35 U.S.C. §103(a) in view of Motamedi, Swanson, Altman, and U.S. Patent No. 5,709,653 to Leone (hereinafter "Leone"). Applicants respectfully traverse.

As set forth above, Motamedi, Swanson, and Altman fail to teach or suggest a method wherein an illumination device comprising a fiberoptic housed within a balloon is inserted to the desired treatment site and illumination is delivered from the fiberoptic through the balloon.

Leone does not remedy these deficiencies. Leone describes a photodynamic balloon catheter that diffuses illumination uniformly over the working area 29 of the balloon. However, there is no motivation to modify Motamedi in view of Leone so as to provide Motamedi's conductor housed within a balloon and delivering illumination from the conductor through the balloon because such a modification would render the device of Motamedi "unsuitable for its intended purpose" and would result in "a change in the basic principle under which [Motamedi] was designed to operate" (see MPEP 2143.01). In particular, providing Motamedi's conductor housed within a balloon would prevent it from advancing beyond the catheter body and penetrating and entering the cardiac tissue.

Lardo et al.  
U.S.S.N. 09/904,182  
Page 9 of 10

Thus, claims 61 and 84 are patentable over Motamedi, Swanson, Altman, and Leone. Claims 64-77 depend from claim 61 and, thus, also are patentable over Motamedi, Swanson, Altman, and Leone. Reconsideration and withdrawal of the rejection is respectfully requested.

**Motamedi, Swanson, Altman, and Rice**

Claim 82 is rejected under 35 U.S.C. §103(a) in view of Motamedi, Swanson, Altman, and U.S. Patent No. 6,200,309 to Rice (hereinafter "Rice"). Applicants respectfully traverse.

As set forth above, Motamedi, Swanson, and Altman fail to teach or suggest a method wherein an illumination device comprising a fiberoptic housed within a balloon is inserted to the desired treatment site and illumination is delivered from the fiberoptic through the balloon.

Rice does not remedy these deficiencies. Rice describes a laser system for irradiating tumor cells in the presence of a photosensitizing compound. The laser system is adapted to cover the entire phototherapeutic spectral region (generally 500-1600nm). Rice does not teach or suggest a method wherein an illumination device comprising a fiberoptic housed within a balloon is inserted to the desired treatment site and illumination is delivered from the fiberoptic through the balloon. Further, even if Rice did describe such a method, there is no motivation to modify Motamedi so as to provide a balloon housing the conductor tip and delivering illumination from the conductor through the balloon because such a modification of Motamedi would render the device of Motamedi "unsuitable for its intended purpose" and would result in "a change in the basic principle under which [Motamedi] was designed to operate" (see MPEP 2143.01). In particular, providing Motamedi's conductor housed within a balloon would prevent it from advancing beyond the catheter body and penetrating and entering the cardiac tissue.

Accordingly, Applicants respectfully submit that claim 61 is patentable over Motamedi, Swanson, Altman, and Rice. Claim 82 depends from claim 61 and, likewise, is patentable over Motamedi, Swanson, Altman, and Rice. Reconsideration and withdrawal of the rejection is respectfully requested.

Lardo et al.  
U.S.S.N. 09/904,182  
Page 10 of 10

RECEIVED  
CENTRAL FAX CENTER

JUL 12 2007

CONCLUSION

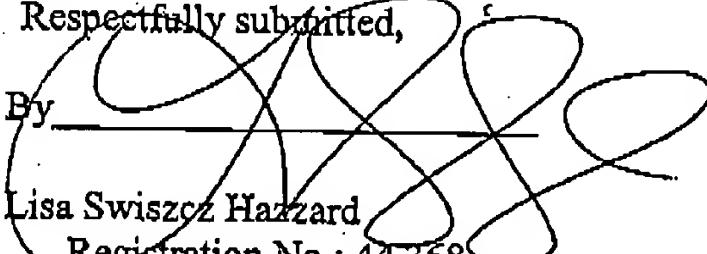
Applicant respectfully requests early consideration and allowance of the subject application.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. 04-1105.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Dated: July 12, 2007

Tel. No.: (617) 517-5512  
Fax No.: (617) 439-4444

Respectfully submitted,  
By \_\_\_\_\_  
  
Lisa Swiszcz Hazard  
Registration No.: 44,368  
Attorney for Applicant  
EDWARDS ANGELL PALMER & DODGE LLP  
P.O. Box 55874  
Boston, Massachusetts 02205-5874